REMARKS

The inventor and his representative acknowledge, with appreciation, the courtesy extended by the Examiner in granting an interview on May 21, 2008.

The Examiner has requested election and restriction between Group I, namely claims 27-74 and 81-122 and Group II, namely claims 75-80. Applicant provisionally elects to prosecute the claims of Group I and reserves the right to file a divisional application or take such other appropriate measures as deemed necessary to protect the invention of Group II. This confirms the provisional election made by telephone on January 17, 2008.

Claims 94-100 were objected to under 37 C.F.R. 1.75© as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. Claims 94-100 have herein been amended to remove the multiple dependency. Amended claims 94-100 each depend on claim 27 which is not a multiple dependent claim. Accordingly, examination of claims 94-100 on their merits is respectfully requested.

Claims 27, 32, 33-43, 47-50, 60-63, 65-74, 110-115 and 118-122 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Gonella* in view of *Dal Farra et al.* Claims 120 and 121 have been canceled herein.

Initially and as discussed during the interview, it is noted that the present invention provides a stable, high-concentration, hormone concentrate in solution form wherein the concentrate can be readily diluted by a compounding pharmacist to create a variety of customized bio-identical hormone replacement therapy (BHRT) products in a non-solid form (i.e. ointments, creams, gels, or pastes) (para. 18). The present invention overcomes the cumbersome problem of having to use a number of precautionary measures to enable the safe use of high concentration powdered hormones that are

presently used in the compounding process (para. 8-16). Further, the concentrations of hormone claimed in the invention are significantly greater than disclosed in the cited references.

It is submitted that the purpose of the *Gonella* product is to provide a final product, namely an adhesive plaster for transdermal administration. As such, the range of hormone concentration applied by the final product in *Gonella* can only be within the range of 0.5 to 3.0% in order to be effective. In contrast, the present invention I not an end product that is administered to patients, but rather it is a concentrate that can be used by pharmacists in the production of hormone replacement therapies (para. 2 and para. 9). This invention is directed to the field of preparing BHRT pharmaceutical compositions in compounding pharmacies. As such, the present invention requires that there be high concentrations of hormone such as in the range of 3.5% to 80% that can be diluted by the pharmacist to a safe concentration which can then be administered to patients (as per claims 27-122, present application). Administering such a high concentration of hormone to the patient in the manner taught by *Gonella* would be very unsafe to the patient, and in fact *Gonella* teaches away from the use of high concentrations of hormone (col. 2, lines 37-41). In direct contrast, the present invention requires the use of a hormone concentration that is "greater than the accepted physician prescribed concentrations to treat hormone deficiencies" (para. 20, present application). *Gonella* does not disclose nor suggest the use of high concentrations of hormones as are claimed by the applicant.

The Office Action further cites *Dal Farra et al* to support the pharmaceutical agent being solubilized in a pharmaceutically acceptable solvent comprising water, ethanol, propyfene glycol, ethoxy diglycol or mixtures thereof. There are a number of significant distinctions that can be made between the present invention and the teachings of *Dal Farra et al.* The present invention is directed to the field of hormone concentrate solutions for use in the subsequent preparation of diluted hormone

treatments by compounding pharmacists. In contrast, *Dal Farra et al* teach the method of use of a Heat Shock Protein (HSP) inducing compound that is used in limiting the undesirable side effect of retinoids (para. 17). The preferable compound in *Dal Farra et al* is an enzymatic extract from the zooplankton of the species *Artemia salina*, which is a type of brine shrimp (para. 38) and unlike the present invention, is not a hormone. *Dal Farra et al* do not teach nor suggest the use of high concentrations of hormone.

Thus, the combination of the two cited references does not disclose the features claimed by the applicant. The resulting product from the combined references would not be a concentrated hormone pharmaceutical composition.

Claims 27-32, 35, 36, 39-53, 60-64, 81-91 and 102-109 were rejected under 35 U.S.C. 101(a) as being unpatentable under *Schultz et al*. *Schultz et al* is described as disclosing a steroid hormone composition comprising estrogen and progestin, a composition comprising an excipient such as lactose and a composition containing disintegrants, lubricants and colorants. However, there are a number of distinctions between the present invention and the *Schultz et al* application. The *Schultz et al* application relates to a dry granulation or direct compression process (para. 15) that results in a steroid hormone product having an improved dissolution profile (para. 13). The preparation of a powdered hormone product would be useful for preparation of a capsule or tablet form of hormone product. Unlike the present invention, the *Schultz et al* application does not teach the use of a concentrated solution. Furthermore, the *Schultz et al* application requires the use of a volatile solvent, such as ethanol (Example 1, para. 42; Example 2, para. 52; Example 4, para. 77) as such solvents would evaporate quickly. The method of handling the product formed in the *Schultz et al* application with the volatile solvent bears the same compounding handling problems as described by the applicant

in para. 8. The use of non-volatile solvents, as used in the present invention, overcomes the handling problems of the *Schultz et al* application by allowing the pharmacist to use a more stable solution that does not evaporate as quickly as the *Schultz et al* product. As well, the *Schultz et al* application limits the user to one concentration of the hormone in the powdered product. In direct contrast, the stability of the solvents used in the present invention allows the pharmacist to more easily adjust the hormone concentrations (para. 60, present application).

Claims 27-32, 35, 36, 39, 54-59, 116 and 117 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Rosario-Jansen et al* (corrected publication is 2007/0190120). *Rosario-Jansen et al* disclose topical administration of testosterone and a carrier vehicle. Unlike the present invention, the *Rosario-Jansen et al* application provides a final product that is directly administered to the patient for the treatment of persons having elevated SHBG levels (abstract and Example 1). As well, *Rosario-Jansen et al* teach away from the use of high dose concentrations of hormone (para. 89) and provides a comparatively smaller range of low concentrations (para. 59). The Office Action concedes that the reference does not disclose the claimed concentration of the hormone as claimed.

Claims 27-32, 35, 36, 39, 60-64, 118 and 119 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Nelson*. The reference discloses a typical progesterone composition comprising progesterone and emu oil. The Office Action admits that *Nelson* does not disclose the claimed concentration of hormone. Unlike the present invention which is directed to a material that is used in the process of preparing a final hormone product, the *Nelson* reference is directed squarely to a final product that is administered to a patient for hormone therapy. As outlined above, the present invention requires the use of a hormone concentration that is "greater than the accepted physician prescribed concentrations to treat hormone deficiencies" (para. 20, present application). The

concentrations of the hormone provided in the *Nelson* reference (col. 2, lines 41-46) or 400 – 500 mg/ounce wt. result in approximately 0.016% concentration of hormone. This amount is significantly less than the lowest concentration of hormone taught by the present invention (3.5%). As the use of a 3.5% concentration of hormone would far exceed an administrable dose concentration for direct application to a patient, it is not likely that the person of skill in the art would experiment so broadly as to arrive at the range of concentrations taught by the present invention. Looking solely at the concentrations taught by the present invention, it would be apparent to the person of skill in the art that the cited references and the present invention are in different fields. The cited references are directed to a final product administrable to a patient, and the present invention is directed to an in-process material.

With respect to independent claim 65, it is submitted that neither *Gonella, Dal Fara et al*, or any of the other cited references suggest or disclose measuring the hormone and the solvent using a balance in a clean room nor using an industrial scale mixer. Allowance of independent claim 65 and claims 66-79 dependent therefrom is respectfully requested.

For the above-cited reasons it is submitted that the claims, as amended, are distinguishable from the cited references. Lifting of these references as a basis for rejection and allowance of the claims is respectfully requested.

It appears that all matters have been addressed satisfactorily, and that the case is now in condition for a complete allowance, and the same is respectfully requested.

However, if the Examiner has any comments or questions, or has any suggestions as per MPEP 707.07 (d) and (j), for putting the case in condition for final allowance, he is respectfully urged to

contact the undersigned attorney-of-record at the telephone number below, so that an expeditious resolution may be effected and the case passed to issue promptly.

Respectfully submitted,

May 23, 2008
Date

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